

REMARKS / ARGUMENTS

Applicant respectfully requests reconsideration of the above-identified application. Amendments to the specification address typographical errors. No new matter is added by virtue of the specification and claim amendments.

Claims 1-29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. In particular, the Examiner notes that the use of "said edge" at claim 1, line 12 is vague since both side edges and forward edges have been recited. Applicants have amended claim 1 to clarify that the "edge" is the "forward edge" of the tip region which is positively recited at claim 1, line 10. The Examiner also states that it is unclear whether the pursuing cable assembly extends through only one leaf or plural leaves. In response, Applicants have amended claim 1 at line 17 to clarify that the pursuing cable assembly extends through "said cable receiving aperture of each said leaf." Finally, the Examiner cites the term "pursively" at line 19 as being vague. That term has been deleted.

Claims 1-5 and 7 stand rejected under 35 U.S.C. 102(e) as being anticipated by Applicants' own prior invention, namely, Eggers, et al., U.S. Patent No. 6,471,659, published February 14, 2002 and issued October 29, 2002 (the '659 patent). In particular, the Examiner states that "The eyelet structure as shown in Figure 23 has a substantially constant width and therefore reads upon the claimed structure."

Applicants have amended claim 1 to recite that the tissue capture component has "an eyelet structure extending forwardly from the location of said forward edge with an eyelet width extending substantially continuously along said leaf length effective to withstand tissue cutting loads".

Contrary to the Examiner's assertion, the eyelets shown in the '659 patent, e.g., Figure 23, do not have a substantially constant width as now recited in claim 1. Because it is necessary to twist the eyelet structures to achieve necessary cable play-out or deployment, the '659 eyelet structures are configured with a narrow neck portion of 0.020 inch width and an overall length of about 0.080 inch. See Figs 14A-14C of the present application, which are identified as "Prior Art." With this configuration, the eyelets are twisted at the neck portion. While this configuration provides for ease in manufacturing, test experience with the capture components utilizing compressed porcine tissue has determined that, where the retrieval procedures encounter very dense breast tissue, the eyelets may fail by folding back. This is particularly the case where the instruments are structured for larger capture diameters, i.e., in the range of from about 15mm to about 25mm. See Application, page 5, lines 17-26.

Looking to Figs. 6A-6C of the present application, it may be seen that the neck portion has been eliminated and the improved eyelet has a substantially constant width, W , along its entire length, L . In Fig. 6A, eyelet 244a has a width extending between edges 242 and 252. That width is substantially constant from the location of adjacency 240 of edge 238 with eyelet edge 242. Figs. 16A-C, 17A-C, 18A-18C, and 19A-19C illustrate different embodiments of the improved eyelet structure, yet each has an eyelet width that extends substantially constantly along its entire length.

With the above-described structural change, the cable manipulating eyelet structures employed at the tips of multiple leaf assemblies are capable of withstanding bending stresses imposed during cutting movement through dense tissue. While exhibiting increased but constant widthwise dimensions with minimized lengths, the structures remain desirably small in size but exhibit substantially improved structure integrity when subjected to surgical activity within the environment of very dense tissue. See Application, page 5, line 31 to page 6, line 4.

The above-noted structural differences between the previous necked configuration and the current constant width configuration were the result of extensive structural analysis conducted by Applicants in an attempt to balance manufacturing and performance considerations. For each improved eyelet structure, Applicants developed a force analysis model used to determine the bending and compressive forces at which the eyelet structure of Figs. 6A-6C will deflect or fold-back the eyelet through a range of angles. Based on these force analysis models, Applicants derived a series of formulas for calculating the bending and compressive forces for each eyelet configuration. Computed forces for the embodiment illustrated in Figs. 6A-6C and for the prior art embodiment shown in Figs. 14A-14C are set forth in Table 1, which reveals that the strength performance values of the improved eyelet structure are almost twice that of the prior art design. For the embodiments shown in Figs. 16-19 of the present application, the forces required to elastically deflect the eyelet over a range of angles are set forth in Table 2. These results further illustrate the improved strength characteristics of the constant width eyelet over the prior art design.

Claims 2-5 and 7, each of which depend directly or indirectly from claim 1, should be considered patentable for the reasons given above in connection with claim 1. Claims 4 and 7 have been amended to provide correct antecedent basis in view of the amendment of claim 1.

Applicants note with appreciation that the Examiner has allowed claims 30-45.

In view of the amendments made to address the §112 rejection and the novelty and non-obviousness arguments presented above, Claim 1 should be considered allowable. Claims 6 and 8-29 also should be allowed in their present form in view of the amendments and arguments

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made with respect to claim 1. Applicants, therefore, earnestly solicit issuance of a Notice of Allowance.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited on February 21st, 2005 with the United States Postal Service as first class mail in an envelope addressed to:

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